



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-3163]

Agency Information Collection Activities; Proposed Collection; Comment Request; Physician Interpretation of Information About Prescription Drugs in Scientific Publications Versus Promotional Pieces

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the *Federal Register* concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on research entitled "Physician Interpretation of Information About Prescription Drugs in Scientific Publications vs. Promotional Pieces." This study will examine important public health issues in professionally directed prescription drug print promotion.

DATES: Submit either electronic or written comments on the collection of information by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL*

*REGISTER*]. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

#### *Electronic Submissions*

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

#### *Written/Paper Submissions*

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

*Instructions:* All submissions received must include the Docket No. FDA-2018-N-3163 for "Physician Interpretation of Information About Prescription Drugs in Scientific Publications vs. Promotional Pieces." Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as

"confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-7726, [PRAStaff@fda.hhs.gov](mailto:PRAStaff@fda.hhs.gov).

*For copies of the questionnaire contact:* Office of Prescription Drug Promotion (OPDP) Research Team, [DTCresearch@fda.hhs.gov](mailto:DTCresearch@fda.hhs.gov).

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the *Federal Register* concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this

requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

#### Physician Interpretation of Information About Prescription Drugs in Scientific Publications

#### Versus Promotional Pieces

OMB Control Number 0910-NEW

#### I. Background

Section 1701(a)(4) of the Public Health Service Act (42 U.S.C. 300u(a)(4)) authorizes FDA to conduct research relating to health information. Section 1003(d)(2)(C) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 393(d)(2)(C)) authorizes FDA to conduct research relating to drugs and other FDA regulated products in carrying out the provisions of the FD&C Act. Under the FD&C Act and implementing regulations, promotional labeling and advertising about prescription drugs are generally required to be truthful, non-misleading, and to reveal facts material to the presentations made about the product being promoted (see FD&C Act section 201(n) and 502(a) and (n) (21 U.S.C. 321(n) and 352(a) and (n)); see also 21 CFR 202.1). The proposed collection of information will investigate how physician perception of prescription

drug information is influenced by variations in information context (presence of graphical elements and information delivery vehicle--medical journal abstract or sales aid), methodologic rigor of the underlying clinical study (high or low), and time pressure (present versus absent). This will contribute to the body of knowledge on perceptual influences, including information summarized below.

*A. Ways in Which Information Context and Study Quality May Influence Perceptions*

Physicians gain knowledge about medical product uses from a variety of information vehicles including peer-reviewed journal articles, compendia, continuing medical education, and physician-directed promotion by or on behalf of manufacturers. Peer-reviewed scientific publications may report the results of a variety of studies, employing a wide range of methodologies with varying levels of quality. As a result, information of varying quality is disseminated to the field. Physician detailing sometimes includes information derived from peer-reviewed research that, in this context, serves a dual purpose: to both inform and market a particular product (Ref. 1).

Prior research has examined some impacts of study quality and funding source on physician perception. For example, research by Kesselheim et al. (Ref. 2) on study abstracts examined how methodologic rigor (high, medium, low) and information about the source of funding (industry, National Institutes of Health, none) affected physician perceptions of study quality, prescribing intentions, and interest in reading the full article. Results indicated physician participants were able to distinguish between levels of methodologic rigor. Physicians also used information about the funding source to distinguish materials: they reported less willingness to prescribe the drugs or read the full study from trials funded by industry, regardless of study

quality. Thus, funding source was a contextual factor that impacted physicians' perceptions of the information.

Research has also shown that physician prescribing behavior can be influenced by the context in which the information is delivered. Spurling et al (Ref. 3) examined the way in which information from a pharmaceutical company was delivered (using conventional promotional techniques such as sales rep visits, journal advertisements, or attendance at pharmaceutical-sponsored meetings versus not using conventional promotional techniques such as participation in company sponsored trials and representatives' visits for nonpromotional purposes) and prescribing outcome across 58 studies. They found conventional promotional techniques were associated with an increase in prescribing and a decrease in prescribing quality. We are proposing to test a different type of contextual factor in this study: whether the drug information appears in a medical journal abstract or a sales aid.

#### *B. Ways in Which Graphics May Influence Perceptions*

Promotional materials about prescription drugs that are directed toward physicians often include a variety of visual elements beyond simple text. In a study of professionally directed prescription drug brochures left for physicians by pharmaceutical representatives, researchers found 95 percent contained a visual graphic (including bar charts, line graphs, pie charts, arrows) accompanying the presentation of data (Ref. 4). An analysis of professionally directed prescription drug print advertisement in medical journals found 80 percent of the ads contained some type of image and 21 percent contained graphics. A group of two physicians and one pharmacist judged these ads. This group found that of those ads that contained images, 58 percent contained images that minimized the risks of the product and 24 percent of the images in the ads misled about product efficacy (Ref. 5).

### *C. Ways in Which Time Pressure May Influence Perceptions*

We are also interested in how time pressure may impact physician perceptions. Time pressure can impact processing of information (e.g., accuracy and speed) as well as decision making. Physicians are often under pressure to split their work time between myriad duties that may include clinical care, research, mentoring, teaching, and administrative duties (Ref. 6). Individuals under time pressure tend to rely on previously formed attitudes for decision making and have less cognitive capacity to process information (Refs. 7 and 8). This results in different decisions depending on the amount of time available (Ref. 9). Research suggests that in situations with high time pressure or increased ambiguity, experts use intuitive decision making strategies rather than structured approaches (Refs. 10 and 11). Physicians may therefore tend to rely on intuitive processes rather than evidence-based information under time pressure.

Research has also found that under time pressure, physician adherence to clinical practice guidelines concerning history taking and advice giving can be compromised (Ref. 12). Moreover, one study that assessed the reading habits of physicians found that given the limited time available for critical reading, these practitioners relied heavily on abstracts and prescreening of articles by editors to ensure they received rigorous and useful information (Ref. 13). Thus, time pressure is an element of physicians' practice environment that can impact decision making and, consequently, quality of healthcare delivered.

## **II. Proposed Study**

We propose to investigate how physician perception of professional prescription drug communications is influenced by variations in information context, methodologic rigor of the underlying clinical study, and time pressure. We propose to test three different contextual presentations of drug information (medical journal abstract, sales aid without graphic design



elements, sales aid with graphic design elements), and two types of study methodological rigor used by Kesselheim et al. (classified as high or low; Ref. 2). We have chosen to test a mock sales aid presentation and a medical journal abstract to examine the potential differences in perception that may arise by presenting the same information in different vehicles. Mirroring the time constraints of practicing physicians, we will examine the role of time pressure by randomly assigning half of the study participants to a limited amount of available time to read the materials. Table 1 describes the study design.

Table 1.--Study Design

			Information Context		
			Medical Journal Abstract	Sales Aid without graphic design elements	Sales Aid with graphic design elements <sup>2</sup>
Limited Time to Read	Methodological Rigor <sup>1</sup>	High			
		Low			
Unlimited Time to Read		High			
		Low			

<sup>1</sup> As defined by Kesselheim et al. (Ref. 2).

<sup>2</sup> For example, colors and background images.

For this proposed study, voluntary participants will be board-certified internists. To examine differences between experimental conditions, we will conduct inferential statistical tests, such as analysis of variance. With the sample size described in this document, we will have sufficient power to detect small-to-medium sized effects in the main study.

We plan to conduct one pretest with 158 voluntary participants and one main study with 566 voluntary participants. The studies will be conducted online. The pretest and main studies will have the same design and will follow the same procedure. Participants will be randomly assigned to 1 of 12 test conditions (see table 1). Following exposure to the stimuli, they will be asked to complete a questionnaire that assesses comprehension, perceptions, prescribing

intentions, and demographics. We anticipate analyzing the data as a full factorial design (main effects and interactions) with two primary comparisons for the information context independent variable: journal abstract versus sales aid without graphics, and sales aid without graphics versus sales aid with graphics. We will also do an exploratory comparison of journal abstract versus sales aid with graphics. In the pretest, participants will also answer questions about the study design and questionnaire.

This study will be conducted as part of the research program of FDA's Office of Prescription Drug Promotion (OPDP). OPDP's mission is to protect the public health by helping to ensure that prescription drug information is truthful, balanced, and accurately communicated, so that patients and healthcare providers can make informed decisions about treatment options. OPDP's research program supports this mission by providing scientific evidence to help ensure that our policies related to prescription drug promotion will have the greatest benefit to public health. Toward that end, we have consistently conducted research to evaluate the aspects of prescription drug promotion that we believe are most central to our mission, focusing on three main topic areas: advertising features, including content and format; target populations; and research quality. Through the evaluation of advertising features we assess how elements such as graphics, format, and disease and product characteristics impact the communication and understanding of prescription drug risks and benefits; focusing on target populations allows us to evaluate how understanding of prescription drug risks and benefits may vary as a function of audience; and our focus on research quality aims at maximizing the quality of research data through analytical methodology development and investigation of sampling and response issues. This study falls under the topic of both target populations and advertising features.

Because we recognize the strength of data and the confidence in the robust nature of the findings are improved through the results of multiple converging studies, we continue to develop evidence to inform our thinking. We evaluate the results from our studies within the broader context of research and findings from other sources, and this larger body of knowledge collectively informs our policies as well as our research program. Our research is documented on our homepage, which can be found at:

<https://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cder/ucm090276.htm>. The website includes links to the latest *Federal Register* documents and peer-reviewed publications produced by our office. The website maintains information on studies we have conducted, dating back to a direct-to-consumer survey conducted in 1999.

FDA estimates the burden of this collection of information as follows:

Table 2.--Estimated Annual Reporting Burden<sup>1</sup>

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Pretest screener	197	1	197	0.03 (2 minutes)	6
Main Study screener	700	1	700	0.03 (2 minutes)	21
Completes, Pretest	158	1	158	0.33 (20 minutes)	53
Completes, Main Study	566	1	566	0.33 (20 minutes)	187
Total	1,621		1,621		267

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

### III. References

The following references are on display with the Dockets Management Staff (see ADDRESSES) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; these are not available electronically at <https://www.regulations.gov>. as

these references are copyright protected. FDA has verified the website addresses, as of the date this document publishes in the *Federal Register*, but websites are subject to change over time.

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4. Cardarelli, R., J.C. Licciardone, and L.G. Taylor, "A Cross-Sectional Evidence-Based Review of Pharmaceutical Promotional Marketing Brochures and Their Underlying Studies: Is What They Tell Us Important and True?" *BMC Family Practice*, 7:13, 2006.
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7. Alison, L., B. Doran, M.L. Long, et al., "The Effects of Subjective Time Pressure and Individual Differences on Hypotheses Generation and Action Prioritization in Police Investigations," *Journal of Experimental Psychology. Applied*, 19:83-93, 2013.

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13. Saint, S., D.A. Christakis, S. Saha, et al., "Journal Reading Habits of Internists," *Journal of General Internal Medicine*, 15:881-884, 2000.

Dated: October 11, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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